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STAKEHOLDER NEWSLETTER

Message from the Deputy Administrator

Hello! APHIS' Biotechnology Regulatory Services' (BRS) has made significant progress on some key initiatives in the short time that I have been the program's Deputy Administrator since January of this year. We are proud to announce that BRS received ANSI-ASQ National Accreditation Board (ANAB) International Organization for Standardization (ISO) 9001:2000 Certification this past June. This is a significant accomplishment for the program, indicating that the quality management system for our administrative process for permitting meets or exceeds the ISO standards for quality management.

We are also making significant progress on the proposed regulatory revisions to APHIS regulations 7CFR part 340. The upcoming regulatory revisions are our highest priority and we are working to meet the needs of the Agency, Federal regulatory officials, our stakeholders, and the public as we move forward with the proposed rule in the upcoming months. As part of this effort, we will be holding three public meetings to gain feedback on the proposed rule. We will provide details about the meetings as they become available.

Additionally, we continue to work closely with the Food and Drug Administration (FDA) on how the Federal government will regulate the technology of transgenic animals. As we move forward in evaluating our complementary authorities under the Animal and Plant Health Protection Act with FDA, we will be looking to the public to gain input on the livestock health risks and what role our agency should play. The Executive Branch of government continues to discuss the timeframe surrounding the FDA and APHIS publications on this subject.

I am excited about the progress on these and some other important program efforts. I invite you to review an update on BRS' initiatives over the past several months. We hope you find this stakeholder update informative, and encourage you to visit our Web site (<http://www.aphis.usda.gov/biotechnology>) for our latest news and information.

If you have not already done so, we also invite you to register with our on-line BRS stakeholder registry to ensure that you receive all future stakeholder updates at: <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf>.

Sincerely,
Michael Gregoire
BRS Deputy Administrator



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BRS Achieves International Organization for Standardization (ISO) Certification

On June 5, APHIS' Biotechnology Regulatory Services (BRS) received its official Certificate of Registration from the independent auditor BSI Management Systems indicating its quality management system (QMS) meets or exceeds all requirements of the internationally recognized ISO 9001:2000 standard. The ISO 9001:2000 standard provides a set of standardized requirements for quality management systems, and represents an international consensus on good quality management practices. BRS' QMS includes within its scope the coordination and administration of the review and issuance of notifications, permits, and information for genetically modified organisms under Title 7 Code of Federal Regulations (CFR) Part 340.

This is a major step forward for BRS, as the scope of the QMS not only includes quality management of the administrative review and processes of the permit staff, but also quality management of the process followed by the program's biotechnologists. Receiving formal recognition, via ISO 9001 certification, was the culmination of the dedication and hard work by everyone within the scope of the QMS and is a significant strategic milestone for BRS by adopting a process approach to leveraging best practices, improving product and service quality, and maximizing program efficiency. You can view the ISO certificate, as well as the BRS Quality Management System Manual at:

http://www.aphis.usda.gov/biotechnology/news_iso.shtml.

BRS is Guided by New Strategic Plan

BRS recently developed a new strategic plan that will serve to provide us with direction as we move forward over the next 5 years. BRS leadership engaged staff and stakeholders in developing a plan that records the organization's plan for the future – our vision of what we want BRS to become, the mission and values we share, the challenges facing us and how we will overcome them, and what we hope to achieve in the next 5 years. BRS will use this document to guide our internal planning and offer it to our partners to communicate and coordinate our joint efforts. We will also provide this plan to stakeholder organizations, customers, and interested members of the public so that they may understand and learn about our efforts. The new BRS strategic plan is located on our website at:

<http://www.aphis.usda.gov/biotechnology/about.shtml>.

APHIS to Launch Biotechnology Quality Management System Pilot Project

In fall 2008, BRS will launch a Pilot Development Project for its Biotechnology Quality Management System (BQMS). BQMS is a voluntary compliance assistance program that will help universities, small businesses, and large companies develop sound management practices to

enhance compliance with regulatory requirements for field trials and movement of regulated genetically engineered organisms.

APHIS is currently developing the draft audit standard for the BQMS program and a series of guidelines to assist participants in utilizing this compliance assistance program to proactively comply with APHIS regulations. APHIS is presently conducting a technical review of the BQMS audit standard and guidelines with audit-industry experts and expects to complete this effort this summer. Following the review, the Pilot Development Project will test the applicability of the BQMS standard and accompanying guidelines, and assist APHIS in further development of a quality program for its customers. APHIS' goal for the pilot project is to provide another avenue for continuous improvement by obtaining feedback from participants on strengths and areas for improvement to the standard and the guidelines prior to full implementation of the system.

APHIS will also conduct stakeholder meetings with APHIS permit and notification holders to obtain additional feedback on the BQMS standard and guidelines in the fall/winter of 2008. APHIS will post the draft documents online for stakeholder review and will also publish a Federal Register notice of availability with instructions on how to download documents and submit comments.

APHIS is currently seeking voluntary participants for the Pilot Development Project that will serve as a broad representation from its regulated community. By serving as a participant, you will review the BQMS process and provide critical feedback. Specifically, participants will test the feasibility of the BQMS standards and guidelines by developing and implementing a quality management system for their organization that proactively manages regulated movement and field releases. The quality management system will demonstrate an organization's commitment to regulatory accountability, increased transparency, and identification and implementation of measures to minimize the occurrence of compliance infractions. Participants will include representation from one large corporate business (greater than 50 employees), one small business (less than 15 employees), and one academic institution. If you are interested in submitting a proposal to participate, please go to:

http://www.aphis.usda.gov/biotechnology/news_bqms.shtml.

Farm Bill Calls for Improvements in Biotechnology Oversight

BRS is working to address the requirements of the 2008 U.S. Farm Bill, which directs USDA to improve management and oversight of biotechnology. The U.S. farm bill is passed every several years and serves as the primary agricultural and food policy tool of the Federal government. The new farm bill, known as the Food, Conservation, and Energy Act of 2008, replaces the last farm bill which expired in September 2007. By fall 2009, APHIS must take action on lessons learned from its LibertyLink rice investigation and from its 20 years of experience in regulating



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biotechnology. The Farm Bill also directs APHIS to issue regulations to improve the management and oversight of articles regulated under the Plant Protection Act. This will likely be achieved by publication of a final rule amending 7 CFR 340.

In accordance with the Farm Bill requirements on lessons learned, APHIS entered into an agreement with the Association of Official Seed Certifying Agencies (AOSCA) in September 2007 to evaluate approaches used in determining isolation distances between genetically engineered (GE) crops and non-GE varieties. BRS is currently reviewing AOSCA's draft report on isolation distances for rice, cotton, alfalfa, corn, wheat, and safflower. APHIS also signed a Memorandum of Understanding with USDA's Agricultural Marketing Service and USDA's Grain Inspection, Packers, and Stockyards Administration in May 2008, which clarifies the roles of each Agency when responding to incidents of low level presence of regulated GE material found in non-GE crops. APHIS is also making significant progress on its proposed biotechnology regulations that we anticipate publishing at the end of this year.

BRS Invites You to its Upcoming Stakeholder Meeting

We look forward to your attendance at our upcoming stakeholder meeting to be held October 15-16, at APHIS headquarters, 4700 River Road, Riverdale MD 20737. We will provide you with an update on changes we have made to our risk assessment and compliance processes over the past couple of years, including:

- ePermits
- Review of Notifications and Permits, including our Revised NEPA Analysis
- Reassessment of Isolation Distances
- Respective Roles of Risk Assessment and Compliance Groups

We will provide additional meeting details as they become available at:

<http://www.aphis.usda.gov/biotechnology/meetings.shtml>.

Planning for the 2009 Permit Season

The 2009 growing season is fast-approaching. We recommend that applicants submit their 2009 permits and/or notifications promptly. Early submission allows BRS to optimally plan resources to efficiently review applications and complete necessary documents, including environmental assessments, in time to meet planting requests. We encourage applicants to ensure that their application is complete to avoid delays in review and approval. APHIS can not assure timely approval of permits received less than 120 days before planting. Also, please keep in mind,



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applications that involve preparation of an environmental assessment will require additional time beyond the 120 days.

As BRS develops its business plan for 2009, we will look at ways to increase our efficiency and maximize the resources we devote to our core functions, including the processing of notifications, permits, and petitions. We encourage our regulated community to take the time to meet with us to inform us of their long term plans so that we can better prepare for future requests. As we move forward in our planning, we will continue to communicate with you about this important issue. If you have questions about the permit/notification process, please send an e-mail to biotechquery@aphis.usda.gov.

LOOK FOR THESE NEW WEB UPDATES!

- Overview of the BRS Inspection Process with Example Questions (http://www.aphis.usda.gov/biotechnology/compinsp_process.shtml)
- Sample Chart of Field Test Data (<http://www.aphis.usda.gov/biotechnology/status.shtml>)
- All BRS Stakeholder Newsletters with a Stakeholder Registry Link (<http://www.aphis.usda.gov/biotechnology/library.shtml>)

BRS Employee Spotlight

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

Employee: David Reinhold

Position:

Chief, Communication and International Affairs Branch, Policy Coordination Program

Time with BRS:

3 months – I joined BRS in April 2008 after spending time working with BRS on two different detail assignments in 2007.

Activities prior to joining BRS:

I worked for APHIS Wildlife Services for 15 years, with the last 7 years primarily focused on environmental compliance activities. During my tenure, I was stationed in Mississippi, North Carolina, and Maryland, and held positions in both the operational and research divisions.

Education:

I have a B.S. degree in Zoology from Southern Illinois University.

Job Description:

I am responsible for coordinating and managing all BRS outreach, capacity building, and international policy activities.



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Proudest Accomplishment:

Most recently, the completion of APHIS Track II Leadership Development Program. This 18 month course provided me the opportunity not only to learn more about APHIS, but also to learn more about myself. I was professionally challenged by taking on projects and assignments outside of my technical skills and abilities. I also learned how to be more effective when working with a variety of people within and outside of APHIS. As a result, I have become more confident in my abilities to lead and manage a diverse workforce.

What motivates you about your job:

Very simply, public service, not only in the sense of serving the American public, but also serving the needs of those who work for the government. I truly find much enjoyment in seeing my staff and fellow co-workers succeed at their jobs. Having the opportunity to help others succeed and reach their true work potential is what motivates me to become a better supervisor and program manager.

Administrative Update

Beverly (Bev) Simmons is the new Associate Deputy Administrator for Emerging and International Programs. Bev comes to BRS from USDA's Foreign Agricultural Service where she served as Assistant Deputy Administrator for the Office of Scientific and Technical Affairs. As Associate Deputy Administrator with BRS, Bev is responsible for developing new programs and initiatives to meet the evolving nature of APHIS' biotechnology regulatory framework and for advancing BRS' international objectives. You can reach Bev at: (301) 734-7324 or by e-mail at Beverly.Simmons@aphis.usda.gov.

The Communication and International Affairs Branch (CIAB) has three new staff members serving to communicate to our stakeholders at home and abroad. David Reinhold is our new CIAB branch chief, Gwen Burnett is our new State and Tribal Liaison, and Andrew Roberts is our new Agriculturalist on the international team. In his new role, David will coordinate and manage all BRS outreach, capacity building, and international policy activities. You can reach David at (301) 734-0660 or by e-mail at David.Reinhold@aphis.usda.gov. In her new position, Gwen will be working closely with State Departments of Agriculture and the National Plant Board to identify communications and coordination needs for the regulation of GE organisms. This partnership is particularly important as we move forward in implementing the new regulations for GE organisms which will be detailed in a proposed rule targeted for publication later this year. You can reach Gwen at (301) 734-0668 or by e-mail at Gwendolyn.L.Burnett@aphis.usda.gov. In his new role, Andrew will work on a variety of international issues, including the Biosafety Protocol and initiatives with the Organization for Economic Cooperation and Development. You can reach Andrew at (301) 734-5689 or by e-mail at Andrew.F.Roberts@aphis.usda.gov.



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We also have three new staff members on our Regulatory Operations staff. Natalia Weinsetel and Wendy Jin are working to help applicants maintain compliance with APHIS regulations, and Andrea Marks who will be working on quality management. Wendy is our Senior Regional Biotechnologist in the eastern region and is responsible for coordinating inspection activities and reviewing inspection reports for quality and compliance issues. You can reach Wendy at (919) 855-7622 or by e-mail at Wendy.Jin@aphis.usda.gov. Natalia joined the Compliance and Inspections Branch as a Senior Regulatory Specialist to work on compliance enforcement after serving on the BRS Environmental Risk Analysis staff for over a year. You can reach Natalia at (301) 734-0809 or by e-mail at Natalia.A.Weinsetel@aphis.usda.gov. Andrea comes to us as a recent graduate of Morehead State University, Morehead, Kentucky and is serving as our career intern on BRS' Biotechnology Quality Management System. You can reach Andrea at (301) 734-8443 or by e-mail at Andrea.K.Marks@aphis.usda.gov.

We also have a new addition to the Policy Coordination staff. Andrea (Andie) Huberty who served on the Environmental Risk Analysis staff for two years is the branch chief of the Regulatory and Environmental Analysis Branch on the Policy Coordination staff. Andrea will lead diverse activities and projects including National Environmental Policy Act analysis and compliance, Endangered Species Act compliance, development of new policies and regulations, and public comment analysis. Andie is also currently the coordinator for the Roundup Ready Alfalfa Environmental Impact Statement and is also is a key member of the team that is drafting the new biotechnology regulations 7 CFR part 340. You can reach Andie at (301) 734- 0485 or by e-mail at Andrea.F.Huberty@aphis.usda.gov.

David Bennett, our valued IT specialist, retired in July after 5 years of dedicated service. Dave served as the BRS database expert, providing us with critical calculations of permitting data. BRS will miss Dave and the expertise that he provided.

Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting <http://jobsearch.usajobs.opm.gov/> and searching for "Biotechnology Regulatory Services" (in quotes).

Have questions about BRS policy and regulations? E-mail us at biotechquery@aphis.usda.gov



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Year-to-Date Submissions Through July 31, 2008

Notifications Acknowledged

166 Importation
222 Interstate Movement
188 Environmental Release
457 Combined Interstate Movement/Release

Permits Issued

29 Importation
33 Interstate Movement
24 Environmental Release
372 Courtesy Permits

0 Petitions/Extensions to Grant Non-Regulated Status Received